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2D SESSION

H. R. 3691

To provide for the establishment of a Prescription Drug Price Review Board to identify excessive drug prices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 20, 1996

Mr. JOHNSON of South Dakota introduced the following bill; which was referred to the Committee on Commerce

A BILL

To provide for the establishment of a Prescription Drug Price Review Board to identify excessive drug prices, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Prescription Drug
5 Consumer Protection Act of 1996”.

6 **SEC. 2. ESTABLISHMENT OF BOARD.**

7 (a) ESTABLISHMENT.—There is established in the ex-
8 ecutive branch the Prescription Drug Price Review Board
9 (hereinafter in this Act referred to as the “Board”).

10 (b) MEMBERSHIP.—

1 (1) NUMBER AND APPOINTMENT.—The Board
2 shall be composed of 5 members appointed by the
3 President, by and with the advice and consent of the
4 Senate, from among individuals—

5 (A) who are recognized experts in the
6 fields of consumer advocacy, medicine, phar-
7 macology, pharmacy, and prescription drug re-
8 imbursement; and

9 (B) who have not worked in the pharma-
10 ceutical manufacturing industry during the 3-
11 year period ending on the date of appointment.

12 (2) INITIAL APPOINTMENTS.—Initial appoint-
13 ments under paragraph (1) shall be made not later
14 than 90 days after the date of the enactment of this
15 Act.

16 (3) TERMS.—

17 (A) IN GENERAL.—Except as provided in
18 subparagraphs (B) and (C), each member shall
19 be appointed for a term of 5 years.

20 (B) TERMS OF INITIAL APPOINTEES.—As
21 designated by the President at the time of ap-
22 pointment, of the members first appointed—

23 (i) 1 member shall be appointed for a
24 term of 1 year;

1 (ii) 1 member shall be appointed for a
2 term of 2 years;

3 (iii) 1 member shall be appointed for
4 a term of 3 years;

5 (iv) 1 member shall be appointed for
6 a term of 4 years; and

7 (v) 1 member shall be appointed for a
8 term of 5 years.

9 (C) VACANCIES.—A vacancy in the Board
10 shall be filled in the manner in which the origi-
11 nal appointment was made. Any member ap-
12 pointed to fill a vacancy occurring before the
13 expiration of the term for which the member's
14 predecessor was appointed shall be appointed
15 only for the remainder of that term. A member
16 may serve after the expiration of the member's
17 term until a successor has taken office.

18 (4) INITIAL MEETING.—The initial meeting of
19 the Board shall be held not later than 90 days after
20 the date on which the first appointments of the
21 members have been completed.

22 (5) CHAIRPERSON.—The President shall des-
23 ignate 1 member of the Board to serve as the chair-
24 person.

25 (6) BASIC PAY.—

1 (A) IN GENERAL.—Members shall be paid
2 at a rate not to exceed the daily equivalent of
3 the maximum annual rate of basic pay payable
4 under section 5376 of title 5, United States
5 Code, for each day during which the members
6 are engaged in the actual performance of the
7 duties of the Board.

8 (B) TRAVEL EXPENSES.—Members shall
9 receive travel expenses, including per diem in
10 lieu of subsistence, in accordance with sections
11 5702 and 5703 of title 5, United States Code.

12 (c) DIRECTOR AND STAFF.—

13 (1) DIRECTOR.—The Board shall have a direc-
14 tor who shall be appointed by the chairperson, sub-
15 ject to rules prescribed by the Board.

16 (2) STAFF.—The chairperson may appoint and
17 fix the pay of such additional personnel as the chair-
18 person considers appropriate, subject to rules pre-
19 scribed by the Board.

20 (3) APPLICABILITY OF CERTAIN CIVIL SERVICE
21 LAWS.—The director and staff of the Board shall be
22 appointed subject to the provisions of title 5, United
23 States Code, governing appointments in the competi-
24 tive service, and shall be paid in accordance with the
25 requirements of chapter 51 and subchapter III of

1 chapter 53 of such title relating to classification and
2 General Schedule pay rates; except that an individ-
3 ual so appointed may not receive pay in excess of
4 the maximum annual rate of basic pay payable for
5 grade GS-15 of the General Schedule.

6 **SEC. 3. POWERS OF BOARD.**

7 (a) **OBTAINING OFFICIAL DATA.**—The chairperson of
8 the Board may secure directly from any Federal agency
9 information necessary to enable the Board to carry out
10 its duties. Upon request of the chairperson, the head of
11 the agency shall furnish such information to the Board
12 to the extent such information is not prohibited from dis-
13 closure by law.

14 (b) **MAILS.**—The Board may use the United States
15 mails in the same manner and under the same conditions
16 as other Federal agencies.

17 (c) **ADMINISTRATIVE SUPPORT SERVICES.**—Upon the
18 request of the chairperson, the Administrator of General
19 Services shall provide to the Board on a reimbursable
20 basis the administrative support services necessary for the
21 Board to carry out its duties.

22 (d) **CONTRACT AUTHORITY.**—The chairperson may
23 contract with and compensate government and private
24 agencies or persons for the purpose of conducting re-

1 search, surveys, and other services necessary to enable the
2 Board to carry out its duties.

3 (e) INVESTIGATIONS.—The Board may make such in-
4 vestigations as it considers necessary to determine whether
5 there is or may be a violation of any regulation promul-
6 gated under this Act and may require or permit any per-
7 son to file with it a statement in writing, under oath or
8 otherwise as the Board shall determine, as to all the facts
9 and circumstances concerning the matter to be inves-
10 tigated.

11 (f) SUBPOENA POWER.—

12 (1) IN GENERAL.—The Board may issue sub-
13 poenas requiring the attendance and testimony of
14 witnesses and the production of any evidence relat-
15 ing to any matter under investigation by the Board.
16 The attendance of witnesses and the production of
17 evidence may be required from any place within the
18 United States at any designated place of hearing
19 within the United States.

20 (2) FAILURE TO OBEY A SUBPOENA.—If a per-
21 son refuses to obey a subpoena issued under para-
22 graph (1), the Board may apply to a United States
23 district court for an order requiring that person to
24 appear before the Board to give testimony, produce
25 evidence, or both, relating to the matter under inves-

1 tigation. The application may be made within the ju-
2 dicial district where the hearing is conducted or
3 where that person is found, resides, or transacts
4 business. Any failure to obey the order of the court
5 may be punished by the court as civil contempt.

6 (3) SERVICE OF SUBPOENAS.—The subpoenas
7 of the Board shall be served in the manner provided
8 for subpoenas issued by a United States district
9 court under the Federal Rules of Civil Procedure for
10 the United States district courts.

11 (4) SERVICE OF PROCESS.—All process of any
12 court to which application is made under paragraph
13 (2) may be served in the judicial district in which
14 the person required to be served resides or may be
15 found.

16 **SEC. 4. FUNCTIONS OF THE BOARD.**

17 (a) GUIDELINES.—The Board shall—

18 (1) develop and publish within 9 months of the
19 date of the establishment of the Board the initial
20 guidelines that the Board will use in determining
21 whether an existing price or an increase in the price
22 of any prescription drug is excessive,

23 (2) develop and publish within 12 months of the
24 date of the establishment of the Board the initial
25 guidelines that the Board will use in determining

1 whether the initial price at which a prescription drug
2 is first sold is excessive, and

3 (3) periodically review the guidelines developed
4 under paragraphs (1) and (2) and make appropriate
5 revisions.

6 (b) DETERMINATIONS AND REVIEWS.—The Board
7 shall—

8 (1) within 24 months of the date of the estab-
9 lishment of the Board, make an initial determination
10 of whether the price of each prescription drug ap-
11 proved for sale on the date of the enactment of this
12 Act is excessive,

13 (2) promptly make an initial determination of
14 whether the price of each prescription drug first ap-
15 proved for sale after the date of the enactment of
16 this Act is excessive,

17 (3) review, on an ongoing basis, each increase
18 in the price of a drug reviewed under paragraphs (1)
19 and (2) to determine if the price increase is exces-
20 sive, and

21 (4) consider whether determinations and re-
22 views similar to the ones carried out under para-
23 graphs (1), (2), and (3) should be made for non-pre-
24 scription drugs and make such determinations and
25 reviews if appropriate.

1 (c) FACTORS.—In making determinations under sub-
2 section (b) as to whether the price of a prescription drug
3 is excessive, the Board shall take into consideration—

4 (1) changes in the producer price index (pub-
5 lished by the Bureau of Labor Statistics of the De-
6 partment of Labor),

7 (2) changes in the prescription drug component
8 of such producer price index,

9 (3) the price at which such drug was sold to
10 wholesalers in the United States during the preced-
11 ing 10 years,

12 (4) the price at which such drug was sold to
13 wholesalers in other countries during the preceding
14 10 years,

15 (5) the price at which other drugs in the same
16 therapeutic class were sold to wholesalers in the
17 United States during the preceding 10 years,

18 (6) the therapeutic potential rating of such
19 drug by the Food and Drug Administration,

20 (7) the percentage of such drug's research and
21 development costs paid by the United States,

22 (8) the cost of manufacturing and marketing
23 such drug, and

24 (9) such other factors as the Board considers
25 relevant.

1 (d) REPORTING.—The Board shall—

2 (1) promptly provide to consumers and health
3 care providers the results of the Board's determina-
4 tions under subsection (b) and the method used in
5 each such determination,

6 (2) provide information to consumers and
7 health care providers regarding prescription drug
8 pricing and price increases by therapeutic class and
9 manufacturer,

10 (3) provide to consumers and health care pro-
11 viders information regarding the Food and Drug Ad-
12 ministration therapeutic potential rating of each pre-
13 scription drug and the percentage of the research
14 and development of each such drug paid by the
15 United States,

16 (4) provide to consumers such other informa-
17 tion as the Board determines will assist consumers
18 in reducing their expenses for prescription drugs,

19 (5) publish an easy to understand consumer's
20 guide to prescription drug prices, including the in-
21 formation described in paragraphs (1), (2), (3), and
22 (4), within 24 months of the date of the establish-
23 ment of the Board and update and publish such
24 guide annually thereafter, and

1 (6) provide to the President and the Congress
2 a report of its determinations under subsection (b)
3 within 24 months of the date of the establishment
4 of the Board and update and report such determina-
5 tions annually thereafter.

6 **SEC. 5. SANCTIONS AND REMEDIES.**

7 (a) HEARINGS.—After making a determination under
8 section 4(b) that the price of a prescription drug or an
9 increase in the price of such a drug is excessive, the Board
10 shall—

11 (1) notify, in writing, the manufacturer of such
12 drug of such determination,

13 (2) fix a date on which a public hearing before
14 the Board respecting such determination shall be
15 held and hold such hearing,

16 (3) request from such manufacturer such addi-
17 tional information as the Board deems necessary for
18 such public hearing, and

19 (4) notify such manufacturer of the Board's
20 recommendation as to the pricing of the drug at a
21 rate which is not excessive.

22 (b) SETTLEMENT.—If, after a public hearing under
23 subsection (a), the Board finds that the price or an in-
24 crease in the price of a prescription drug is not excessive,
25 the Board shall—

1 (1) notify the manufacturer of such drug of the
2 Board's finding, and

3 (2) remove from all publications and reports of
4 the Board after the date of such finding any state-
5 ment that the price or increase in the price of such
6 drug is excessive.

7 (c) PATENT REVOCATION.—If, after a public hearing
8 under subsection (a), the Board finds that the price or
9 an increase in the price of a prescription drug is excessive,
10 the Board shall—

11 (1) notify the manufacturer of such drug of the
12 Board's finding,

13 (2) notify the manufacturer of such drug of the
14 Board's intent to revoke the patent for such drug if
15 the drug is patented or to revoke the patent of an-
16 other drug of such manufacturer if such drug is not
17 patented, and

18 (3) take such action as may be necessary to re-
19 voke a drug patent under paragraph (2) if the man-
20 ufacturer of such drug does not reduce the price of
21 the drug to a level that is not excessive.

22 **SEC. 6. MANUFACTURERS.**

23 Each manufacturer of a prescription drug subject to
24 review under section 4 shall—

(1) provide to the Board such information as the Board may require to make the determinations under section 4, including—

(A) information identifying such drug,

(B) the price at which such drug is being sold or has been sold in any market,

(C) the cost of manufacturing and marketing such drug, and

(D) such other information as the Board considers necessary to be provided in such form and manner and at such time as the Board prescribes by regulation, and

(2) notify the Board immediately of any increase in the wholesale price of any prescription drug marketed by the manufacturer.

SEC. 7. STUDY.

The Board shall engage the Institute of Medicine of the National Academy of Sciences to conduct a study of prescription drug research and development and pricing practices, the difficulties many Americans have in affording prescription drugs, and options for making prescription drugs available to all that need them. Such study shall—

(1) examine Federal incentives for research and development and determine which incentives are

1 most effective and what changes would better en-
2 courage the development of low cost, effective drugs,

3 (2) examine the Federal regulatory process and
4 identify ways it might be streamlined without jeop-
5 ardizing consumer safety,

6 (3) consider whether the authority of the Food
7 and Drug Administration should be enhanced and
8 whether the funding for such agency should be in-
9 creased to improve Federal regulation of drugs,

10 (4) consider steps the United States might take
11 (including possible trade sanctions) to protect manu-
12 facturers of drugs in the United States from product
13 pirating and other unfair trade practices by foreign
14 competitors,

15 (5) consider changes in the patent laws (includ-
16 ing delaying the start of a product's 17 years patent
17 protection until after the product has been approved
18 under the Federal Food, Drug, and Cosmetic Act) to
19 allow manufacturers to charge lower prices and still
20 recoup their research and development costs,

21 (6) consider whether a Board review of non-pre-
22 scription drug prices would have a positive effect on
23 consumer costs of such drugs,

24 (7) consider mechanisms to assist consumers
25 with the high cost of prescription drugs (including

1 providing reimbursement under title XVIII of the
2 Social Security Act for prescription drugs at lower
3 prices negotiated with manufacturers of drugs),

4 (8) examine Federal policies regarding the li-
5 censing of drugs discovered and developed by feder-
6 ally funded researchers and recommend actions that
7 would allow the United States to recoup its costs or
8 to influence the pricing of such drugs, and

9 (9) examine the effects on retail pharmacies of
10 disparities in drug prices wherein the drug manufac-
11 turers charge hospitals, mail order pharmacies, and
12 health maintenance organizations significantly lower
13 prices than those charged wholesalers for such
14 drugs.

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